

## **REMARKS**

Claims 1-5, 7-20, 23-37 and 41-52 are currently pending. Claims 1 and 19 are amended to improve the clarity of the claim language so that the term “stimulation” or “stimulate” is not used in two different contexts. Because this amendment merely clarifies the claim language and does not change the scope of the claims, Applicants respectfully submit that entry of this amendment is proper after final rejection.

## **Claim Rejections - 103**

The pending claims stand rejected under 35 USC 103(a) as being allegedly rendered obvious by John (US 6,066,163) in view of Baudino (US 6,353,762). Applicants request reconsideration of this rejection.

Independent claims 1 and 19 involve exposing a patient to a “first painful sensation” and “measuring the patient’s threshold for pain.” The patient’s brain is then stimulated using the stimulator device. The patient is then subjected to a “second painful sensation” and the patient’s pain threshold is re-measured. The brain stimulation signal is then adjusted in response to the re-measurement of the patient’s pain threshold.

For example, in one particular embodiment, the method of claim 1 can be implemented in the following manner. A neurostimulation device is implanted in a patient’s brain. The patient is then subjected to a painful tactile sensation (e.g., a pinprick) and the patient’s pain threshold to this painful sensation is measured. The neurostimulation is then activated and the patient is again subjected to the same painful sensation (e.g., a pinprick) and the patient’s pain threshold to this painful sensation is measured again. The neurostimulation signal is adjusted according to whether the patient’s pain threshold has been lowered or not.

John describes a method for allegedly optimizing the efficacy of brain stimulation. To achieve this, John uses a feedback loop with adjustment of stimulation parameters based on a statistical analysis of measurements made on the patient (e.g., EEG readings). (See, e.g., col. 3, lns. 22-42). For example, FIG. 2 of John shows a process in which a patient’s reference state is measured and brain stimulation is applied. The stimulation parameters are adjusted based on a comparison of the patient’s present state against the reference state.

However, unlike claims 1 and 19, John does not disclose any steps involving subjecting the patient to a painful sensation, measuring the patient’s pain threshold, and adjusting the stimulation signal in accordance with the patient’s pain threshold. In particular, the discussion of

first and subsequent stimulations at column 2, lines 12-44 of John are referring to electrical stimulation of the brain, not to a painful sensation that is being applied to the patient. At column 9, lines 10-15, John indicates that the patient's pain may be measured, for example, on a scale of 1 to 10. However, measuring a patient's pain is different from the act of exposing the patient to a painful sensation.

Baudino at column 9, lines 21-25 mentions the treatment of chronic pain, but there is no disclosure of any measurement of a patient's pain threshold. Baudino does state "a sensor may be included for generating a signal related to the extent of a physical condition for treating a neurological disorder or pain" (col 2, lns. 57-60), however, a patient's physical condition is different from the act of exposing the patient to a painful sensation. Thus, Baudino does not cure the above-mentioned deficiencies of John.

For at least these reasons, Applicants respectfully submit that claims 1 and 19, and the claims that depend therefrom, are non-obvious over John in view of Baudino. Accordingly, withdrawal of the rejection is respectfully requested.

### **Conclusion**

Although no fees are believed to be due, the Office may charge any additional fees required, or credit any overpayments, to Deposit Account No. 11-0600.

The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Respectfully submitted,

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